

IN THE CLAIMS:

The following is a listing of all the claims as they currently stand. Kindly cancel claims 43-53 and 99-111, amend claims 1-42 and 54-98, and add claims 112-123, as noted below.

1. (Currently amended) A system for analyzing ~~the use of~~ medical devices comprising:
  - a) ~~a~~ geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s);
  - b) ~~a~~ mesh generator that receives ~~the~~ said geometric model of said anatomical feature(s) and ~~the~~ a geometric model of a medical device, and generates a finite element model or mesh ~~incorporating~~ based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
  - e) ~~a~~ stress/strain/deformation analyzer that receives said finite element model or mesh incorporating both said anatomical feature and said medical device, material[[s]] properties of said anatomical feature(s) and said medical device, ~~and~~ load data on said anatomical feature(s) and/or said medical device[[,]] and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of, said medical device.
2. (Currently amended) A ~~The system as defined in of~~ claim 1 wherein said geometric model of said anatomical feature(s) is an idealized geometric model.
3. (Currently amended) A ~~The system as defined in of~~ claim 1 wherein said three-dimensional volumetric data are acquired via CT scan.

4. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said three-dimensional volumetric data are acquired via MRI.

5. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said ~~geometric model of a said~~ medical device is for an endovascular prosthesis.

6. (Currently amended) A ~~The system as defined in~~ of claim 5 wherein said endovascular prosthesis is a ~~transluminally placed endovascular~~ stent graft.

7. (Currently amended) A ~~The system as defined in~~ of claim 5 wherein said endovascular prosthesis is a cardiovascular stent ~~device~~.

8. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said geometry generator is MIMICS.

9. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said mesh generator is TRUEGRID.

10. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said stress/strain/deformation analyzer is DYNA3D.

11. (Currently amended) A ~~The system as defined in~~ of claim 1 wherein said stress/strain/deformation analyzer is NIKE3D.

12. (Currently amended) A ~~The system as defined in~~ of claim 10 wherein said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 +$$

$$a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ \frac{1}{2}K(I_3-1)^2$$

with  $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

13. (Currently amended) A The system as defined in of claim 11 wherein said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ \frac{1}{2}K(I_3-1)^2$$

with  $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

14. (Currently amended) A The system as defined in of claim 1 further comprising a visualization tool that receives said simulated stresses, and strains, and

deformations of ~~on~~ said medical device ~~and anatomical feature~~ from said stress/strain/deformation analyzer and displays one or more of said stresses, and strains, and deformations of ~~on~~ said medical device via visual representation.

15. (Currently amended) A The system as defined in ~~of~~ claim 14 wherein said visualization tool is GRIZ.

16. (Currently amended) A system for analyzing ~~the use of~~ a medical device comprising:

a) a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature(s);

b) a mesh generator that receives ~~the~~ said geometric model of said anatomical feature(s) and ~~the~~ a geometric model of a medical device, and generates a finite element model or mesh ~~incorporating based on~~ both said geometric model of said anatomical feature(s) and said geometric model of said medical device; and

e) a stress/strain/deformation analyzer that receives said finite element model or mesh ~~incorporating both said anatomical feature and said medical device~~, material[[s]] properties of said anatomical feature(s) and said medical device, and load data on said anatomical feature(s) and/or said medical device[[,]] and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of, said medical device.

17. (Currently amended) A The system as defined in ~~of~~ claim 16 wherein said geometric model of said anatomical feature(s) is an idealized geometric model.

18. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said three-dimensional volumetric data are acquired via CT scan.

19. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said three-dimensional volumetric data are acquired via MRI.

20. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said ~~geometric model of a said~~ medical device is ~~for~~ an endovascular prosthesis.

21. (Currently amended) A The system ~~as defined in~~ of claim 20 wherein said endovascular prosthesis is a ~~transluminally placed endovascular~~ stent graft.

22. (Currently amended) A The system ~~as defined in~~ of claim 20 wherein said endovascular prosthesis is a cardiovascular stent ~~device~~.

23. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said geometry generator is MIMICS.

24. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said mesh generator is TRUEGRID.

25. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said stress/strain/deformation analyzer is DYNA3D.

26. (Currently amended) A The system ~~as defined in~~ of claim 16 wherein said stress/strain/deformation analyzer is NIKE3D.

27. (Currently amended) A The system as defined in of claim 25 wherein said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

28. (Currently amended) A The system as defined in of claim 26 wherein said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

29. (Currently amended) A ~~The system as defined in~~ of claim 16 further comprising a visualization tool that receives said simulated stresses, ~~and~~ strains, and deformations of, ~~on~~ said medical device ~~and anatomical feature~~ from said stress/strain/deformation analyzer and displays one or more of said stresses, ~~and~~ strains, and deformations on of, said medical device via visual representation.

30. (Currently amended) A ~~The system as defined in~~ of claim 29 wherein said visualization tool is GRIZ.

31. (Currently amended) A system for analyzing ~~the use of~~ a medical device comprising:

a) a mesh generator that receives a geometric model of an in vitro anatomical feature and a geometric model of a medical device, and generates a finite element model or mesh ~~incorporating~~ based on both said geometric model of said in vitro anatomical feature and said geometric model of said medical device; and

b) a stress/strain/deformation analyzer that receives said finite element model or mesh ~~incorporating both said anatomical feature and said medical device~~, material[[s]] properties of said in vitro anatomical feature and said medical device, ~~and~~ load data on said in vitro anatomical feature and/or said medical device[[,]] and simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations ~~on of~~, said medical device.

32. (Currently amended) A ~~The system as defined in~~ of claim 31 wherein said in vitro anatomical feature is ~~a geometric model of an idealized anatomical feature~~.

33. (Currently amended) A ~~The system as defined in~~ of claim 31 wherein said ~~geometric model of said~~ medical device is ~~for~~ an endovascular prosthesis.

34. (Currently amended) A The system as defined in of claim 33 wherein said endovascular prosthesis is a ~~transluminally placed endovascular~~ stent graft.

35. (Currently amended) A The system as defined in of claim 33 wherein said endovascular prosthesis is a cardiovascular stent ~~device~~.

36. (Currently amended) A The system as defined in of claim 31 wherein said mesh generator is TRUEGRID.

37. (Currently amended) A The system as defined in of claim 31 wherein said stress/strain/deformation analyzer is DYNA3D.

38. (Currently amended) A The system as defined in of claim 31 wherein said stress/strain/deformation analyzer is NIKE3D.

39. (Currently amended) A The system as defined in of claim 37 wherein said DYNA3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

40. (Currently amended) A The system as defined in of claim 38 wherein said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

41. (Currently amended) A The system as defined in of claim 31 further comprising a visualization tool that receives said simulated stresses, and strains, and deformations of, on said medical device and anatomical feature from said stress/strain/deformation analyzer and displays one or more of said stresses, and strains, and deformations of, on said medical device via visual representation.

42. (Currently amended) A The system as defined in of claim 41 wherein said visualization tool is GRIZ.

43. to 53. (Canceled)

54. (Currently amended) A computer method for analyzing a medical device comprising:

- a) acquiring three-dimensional volumetric data of at least one anatomical feature;
- b) generating a geometric model of said ~~three-dimensional volumetric data~~ anatomical feature(s);
- c) receiving data representing a geometric model of a candidate medical device design;
- d) receiving said geometric model of said ~~three-dimensional volumetric data~~ anatomical feature(s);
- e) generating a finite element model or mesh incorporating based on both said geometric model of said anatomical feature and said geometric model of said candidate medical device design;
- f) receiving material properties of said ~~mesh~~ anatomical feature(s) and said candidate medical device design;
- g) receiving load data imposed on of said ~~mesh~~ candidate medical device design and said anatomical feature(s); and
- h) simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of imposed ~~on~~ said candidate medical device design by said load data.

55. (Currently amended) A ~~The method as defined in~~ of claim 54 ~~further comprising wherein~~ the step of simulating stresses, strains, and deformations is performed to a point of failure of said candidate medical device design.

56. (Currently amended) A ~~The method as defined in~~ of claim 54 ~~wherein~~ said three-dimensional volumetric data are acquired via CT scan.

57. (Currently amended) A The method as defined in of claim 54 wherein said three-dimensional volumetric data are acquired via MRI.

58. (Currently amended) A The method as defined in of claim 54 wherein said ~~geometric model of a~~ candidate medical device design is for an endovascular prosthesis.

59. (Currently amended) A The method as defined in of claim 58 wherein said endovascular prosthesis is a ~~transluminally placed endovascular~~ stent graft.

60. (Currently amended) A The method as defined in of claim 58 wherein said ~~endovaseaular~~ endovascular prosthesis is a cardiovascular ~~stent~~ device.

61. (Currently amended) A The method as defined in of claim 54 wherein said geometric model for ~~three-dimensional volumetric data~~ said anatomical feature(s) is generated by a MIMICS software application.

62. (Currently amended) A The method as defined in of claim 54 wherein said step of generating a finite element model or mesh is ~~generated~~ performed by using TRUEGRID.

63. (Currently amended) A The method as defined in of claim 54 wherein said stresses, strains, and deformations are simulated by a DYNA3D software application.

64. (Currently amended) A The method as defined in of claim 54 wherein said stresses, strains, and deformations are simulated by a NIKE3D software application.

65. (Currently amended) A The method as defined in of claim 63 wherein said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

66. (Currently amended) A The method as defined in of claim 64 wherein said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

67. (Currently amended) A The method as defined in of claim 54 wherein said stress/strain/deformation analysis is ~~done~~ performed using a non-linear finite element analysis tool.

68. (Currently amended) A The method as defined in of claim 54 further comprising ~~the step of~~ receiving results of said stress, strain, and deformation analysis into a visualization tool and wherein said visualization tool visually presents ~~the~~ one or more of said strains, stresses, and deformations ~~on of~~ of said medical device.

69. (Currently amended) A The method as defined in of claim 68 wherein said visualization ~~means~~ tool is GRIZ.

70. (Currently amended) A method for analyzing a medical device comprising:

- a) acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;
- b) generating a geometric model of said ~~three-dimensional volumetric data~~ anatomical feature(s);
- c) receiving a geometric model of a candidate medical device;
- d) receiving said geometric model of said ~~three-dimensional volumetric data~~ anatomical feature(s);
- e) generating a mesh ~~incorporating~~ based on both said geometric model of said anatomical feature and geometric model of said candidate medical device;
- f) receiving material properties of said ~~mesh~~ anatomical feature(s) and said candidate medical device;
- g) receiving load ~~data imposed on of~~ data imposed on said mesh anatomical feature(s) and said candidate medical device; and

h) simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of imposed on said candidate medical device.

71. (Currently amended) A The method as defined in of claim 70 further comprising wherein the step of simulating stresses, strains, and deformations is performed to point of failure of said candidate medical device.

72. (Currently amended) A The method as defined in of claim 70 wherein said three-dimensional volumetric data are acquired via CT scan.

73. (Currently amended) A The method as defined in of claim 70 wherein said three-dimensional volumetric data are acquired via MRI.

74. (Currently amended) A The method as defined in of claim 70 wherein said geometric model of a candidate medical device is for an endovascular prosthesis.

75. (Currently amended) A The method as defined in of claim 74 wherein said endovascular prosthesis is a transluminally placed endovascular stent graft.

76. (Currently amended) A The method as defined in of claim 74 wherein said endovascular prosthesis is a cardiovascular stent device.

77. (Currently amended) A The method as defined in of claim 70 wherein said step of generating the geometric model of said anatomical feature(s) means for three-dimensional volumetric data is performed by using MIMICS.

78. (Currently amended) A The method as defined in claim 70 wherein said step of mesh generating means is said mesh is performed by using TRUEGRID.

79. (Currently amended) A The method as defined in of claim 70 wherein said step of simulating dynamic or quasi-static stresses/strains/deformations simulating means is performed by using DYNA3D.

80. (Currently amended) A The method as defined in of claim 70 wherein said step of simulating stresses/strains/deformations simulating means is performed by using NIKE3D.

81. (Currently amended) A The method as defined in of claim 79 wherein said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

82. (Currently amended) A The method as defined in of claim 80 wherein said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ \frac{1}{2}K(I_3-1)^2$$

with  $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

83. (Currently amended) A The method as defined in of claim 70 wherein said stress/strain/deformation analysis is ~~done~~ performed using a non-linear finite element analysis tool.

84. (Currently amended) A The method as defined in of claim 70 further comprising ~~the step of~~ receiving results of said stress, ~~and~~ strain and deformation analysis into a visualization tool and wherein said visualization tool visually presents ~~the~~ one or more of said strains, ~~and~~ stresses and deformations of ~~on~~ said medical device.

85. (Currently amended) A The method as defined in of claim 84 wherein said visualization ~~means~~ tool is GRIZ.

86. (Currently amended) A computer method for analyzing a medical device comprising:

a) receiving data representing ~~an~~ a geometric model of at least one *in vitro* model anatomical feature and a geometric model of a candidate medical device design;

e) generating a finite element model or mesh incorporating based on both said geometric model of said ~~*in vitro* model~~ anatomical feature(s) and said geometric model of said candidate medical device design;

f) receiving material properties of said ~~mesh~~ *in vitro* anatomical feature(s) and said candidate medical device design;

g) receiving load data imposed on ~~of~~ said ~~mesh~~ *in vitro* anatomical feature(s) and said candidate medical device design; and

h) simulating an interaction between said *in vitro* anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformations of imposed on said candidate medical device design by said load data.

87. (Currently amended) A The method as defined in of claim 86 ~~further comprising wherein~~ the step of simulating stresses, and strains and deformations is performed to a point of failure of said candidate medical device design.

88. (Currently amended) A The method as defined in of claim 86 wherein said geometric model of a said candidate medical device design is for an endovascular prosthesis.

89. (Currently amended) A The method as defined in of claim 88 wherein said endovascular prosthesis is a ~~transluminally placed endovascular~~ stent graft.

90. (Currently amended) A The method as defined in of claim 88 wherein said endovascular prosthesis is a cardiovascular stent ~~device~~.

91. (Currently amended) A The method as defined in of claim 86 wherein  
said ~~mesh generating means is~~ step of generating said mesh is performed by using TRUEGRID.

92. (Currently amended) A The method as defined in of claim 86 wherein  
said ~~stress/strain/deformation simulating means is~~ step of simulating stresses, strains, and  
deformations is performed by using DYNA3D.

93. (Currently amended) A The method as defined in of claim 86 wherein  
said ~~stress/strain/deformation simulating means is~~ step of simulating stresses, strains, and  
deformations is performed by using NIKE3D.

94. (Currently amended) A The method as defined in of claim 92 wherein  
said DYNA3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

95. (Currently amended) A The method as defined in claim 93 wherein said  
NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ \frac{1}{2}K(I_3-1)^2$$

with  $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

$a_{ij}$  are material parameters;

$\nu$  is Poisson's ratio;

$K$  is the bulk modulus given as a function of Poisson's ratio; and

$I_1$ ,  $I_2$ , and  $I_3$  are the first, second, and third invariants of the right Cauchy-

Green strain tensor, respectively.

96. (Currently amended) A The method as defined in of claim 86 wherein said stress/strain/deformation analysis is ~~done~~ performed using a non-linear finite element analysis tool.

97. (Currently amended) A The method as defined in of claim 86 further comprising the step of receiving results of said stress, strain, and deformation analysis into a visualization tool and wherein said visualization tool visually presents ~~the~~ one or more of said strains, and stresses and deformations of on said candidate medical device design.

98. (Currently amended) A The method as defined in of claim 97 wherein said visualization ~~means~~ tool is GRIZ.

99-111. (Canceled)

Please add claims 112-123 as follows:

112. (New) The system of claim 1 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses, strains, and deformations of said medical device.

113. (New) The system of claim 1 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

114. (New) The system of claim 16 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate stresses, strains, and deformations of said medical device.

115. (New) The system of claim 16 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

116. (New) The system of claim 31 wherein said stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate stresses, strains, and deformations of said medical device.

117. (New) The system of claim 31 wherein said simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations.

118. (New) The method of claim 54 wherein said simulated stresses, strains, and deformations imposed on said medical device design comprise dynamic or quasi-static stresses, strains, and deformations.

119. (New) The method of claim 86 wherein said simulated stresses, strains, and deformations imposed on said candidate medical device design comprise dynamic or quasi-static stresses, strains, and deformations.

120. (New) The method of claim 86 further comprising receiving data representing a geometric model of an *in vitro* failure mode test.

121. (New) The method of claim 120 wherein said step of simulating comprises simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said *in vitro* failure mode test.

122. (New) The method of claim 120 further comprising varying one or more *in vitro* failure mode test parameters based on an additional step of comparing:

simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data representing said anatomical feature; and

additional simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said *in vitro* failure mode test.

123. (New) The method of claim 122 wherein said one or more *in vitro* failure mode test parameters further comprises test frequency.